Amendment

In the Claims

1. (Original) A method for preparing nanoparticles of a therapeutic, prophylactic or diagnostic agent, comprising

dissolving the agent in a solvent to form a first solution,

providing a non-solvent for the agent which is miscible with the solvent, and

mixing the first solution with the non-solvent to form nanoparticles of the therapeutic, prophylactic or diagnostic agent, wherein the nanoparticles form a population of which at least 95% has a diameter of less than one micron.

2. (Original) The method of claim 1, further comprising adding a surfactant or excipient.

3. (Original) The method of claim 2, wherein the surfactant or excipient is added to the solvent.

4. (Original) The method of claim 2, wherein the surfactant or excipient is added to the non-solvent.

5. (Original) The method of claim 2, wherein the surfactant or excipient is added to the nanoparticles after their formation.

6. (Original) The method of claim 1, wherein the agent is selected from the group consisting of small-molecule drugs, proteins, lipids, polysaccharides, proteoglycans, and polynucleotides.

7. (Original) The method of claim 1, wherein the agent is soluble in water to less than about 0.1% w/v at room temperature.

8. (Original) The method of claim 1, wherein the agent is sufficiently hydrophobic to be insoluble in water.

9. (Original) The method of claim 1, further comprising collecting the nanoparticles by centrifugation, filtration, lyophilization, or spray drying.

10. (Original) The method of claim 1, wherein less than about 1% of the nanoparticles have a diameter of greater than about 1 micron.

11. (Currently amended) A formulation comprising a population ~~population~~ comprising at least 95% nanoparticles of a therapeutic, diagnostic or prophylactic agent having a diameter of less than one micron.

12. (Currently amended) The ~~population~~ formulation of claim 11, wherein the agent is selected from the group consisting of small-molecule drugs, proteins, lipids, polysaccharides, proteoglycans, and polynucleotides.

13. (Currently amended) The ~~population~~ formulation of claim 11, wherein the agent is soluble in water to less than about 0.1% w/v at room temperature.

14. (Currently amended) The ~~population~~ formulation of claim 11, wherein the agent is sufficiently hydrophobic to be insoluble in water.

15. (Currently amended) The ~~population~~ formulation of claim 11, wherein at least 99% of the nanoparticles have a diameter of less than one micron.

~~17~~ 16. (Currently amended) The formulation of claim 11 further comprising bioadhesive enhancing agents.

~~18~~ 17. (Currently amended) The formulation of claim 11 further comprising a dispersant.

~~19~~ 18. (Currently amended) The formulation of claim 11 further comprising a polymer.

~~20~~ 19. (Currently amended) The formulation of claim ~~11comprising~~ 11 comprising a polymer encapsulated agent having bioadhesive agent bound thereto or dispersed therein.

~~21~~ 20. (Currently amended) The formulation of claim ~~17~~ 16, wherein the bioadhesive agent is selected from the group consisting of bioadhesive metal compounds and bioadhesive organic molecules.

~~22~~ 21. (Currently amended) The formulation of claim 11, wherein the nanoparticles are formed by a method comprising

dissolving the bioactive agent in a solvent to form a first solution;

providing a non-solvent for the bioactive agent, wherein the non-solvent is miscible with the solvent; and

mixing the first solution with the non-solvent to form nanoparticles.

~~23~~ 22. (Currently amended) A nano or microparticulate formulation for oral administration of a taxane providing a bioavailability of at least 5% of the bioavailability of the taxane when administered intravenously.

~~24~~ 23. (Currently amended) The formulation of claim ~~23~~ 22 wherein the taxane is paclitaxel.

~~25~~ 24. (Currently amended) The formulation of claim ~~23~~ 22 wherein the taxane is docetaxel.

~~26~~ 25. (Currently amended) The formulation of claim ~~23~~ 22 wherein 90%, by volume or number, of the nanoparticles and microparticles have a diameter of less than five microns.

~~27~~ 26. (Currently amended) The formulation of claim ~~23~~22 wherein 90%, by volume or number, of the nanoparticles and microparticles have a diameter of less than one micron.

~~28~~ 27. (Currently amended) The formulation of claim ~~23~~ 22 wherein the taxane is present in a drug loading of up to 70% by weight.

~~29~~ 28. (Currently amended) The formulation of claim ~~23~~ 22 wherein the taxane is present in a drug loading of between approximately 30 and 70% by weight.

~~30~~ 29. (Currently amended) The formulation of claim ~~23~~ 22 further comprising a surfactant or excipient.

~~31~~ 30. (Currently amended) A method for treating a patient comprising administering a formulation comprising a population comprising at least 95% nanoparticles of a therapeutic, diagnostic or prophylactic agent having a diameter of less than one micron ~~the nanoparticle formulation of claim 11 or 23~~ to a patient.

~~32~~ 31. (Currently amended) The method of claim ~~31~~ 30, wherein the formulation is selected from the group consisting of oral formulations, aerosols, topical formulations, parenteral formulations, and implantable compositions.

~~33~~ 32. (Currently amended) The method of claim ~~31~~ 30, wherein the formulation is administered orally.

~~34~~ 33. (Currently amended) The method of claim ~~31~~ 30, wherein the formulation is administered to the pulmonary system.